APR 17 2014

510(k) Summary

per 21 CFR §807.92

Submitter's Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311
Contact Name and Information	Lisa Mee Senior Regulatory Affairs Specialist Phone: 763-494-1185 Fax: 763-494-2222 e-mail: lisa.mee@bsci.com
Date Prepared	24 Mar 2014
Proprietary Name	Encore™ 26 Advantage Kit
Common Name	Balloon Inflation Kit Comon name of the Kit components: Inflation device, Insertion Tool, Y-Adaptor and Torque Device
Product Code	MAV – Syringe, Balloon Inflation
Classification	Class II, 21 CFR Part 870.1650 – Cardiovascular
Predicate Device(s)	Encore™ 26 Advantage Kit K123214 Nov 13, 2012 SCIMED AVENUE Coronary Guidewire Insertion Tool K922410 Jul 23, 1992
Device Description	The Encore™ 26 Advantage Kit is a Kit of sterile disposable devices intended for use as accessories and percutaneous coronary angiography (PTCA) procedures. They allow for balloon inflation and wire control.
Intended Use	The Encore™ 26 Advantage Kits are intended for use as accessories for percutaneous coronary angiography (PTCA) procedures. They create and monitor balloon inflation and facilitate wire introduction and control. Individual Device Intended Use: • Encore™ 26 Inflation Device: used with balloon dilatation catheters to create and monitor pressure in the balloon, and to deflate the balloon. • Gateway™ Plus Y-Adaptor: used for providing hemostasis around guidewires, balloon dilatation catheters, and other therapeutic devices. • Torque Device: used for guidewire manipulation. • Insertion Tool: used to facilitate the introduction of a guidewire.

Indications for Use

Individual Device Indications for Use:

- The Encore™ 26 Inflation devices are recommended for use with balloon dilatation catheters to create and monitor pressure in the balloon, and to deflate the balloon.
- The GateWay™ PLUS Y-Adapter is recommended for providing homeostasis around balloon dilatation catheters, guidewires, and other therapeutic devices during general intravascular procedures.
- The Torque Device is used for guidewire manipulation during general intravascular procedures.
- The Insertion Tool is used to facilitate the introduction of a guidewire during general intravascular procedures.

Comparison of Technological Characteristics

The proposed Encore™ 26 Advantage Kit Inflation device, Y-Adaptor and Torque device components incorporate substantially equivalent design, fundamental technology, manufacturing processes, packaging, sterilization and intended use as the Inflation device, Y-Adaptor and Torque device components featured in the Boston Scientific predicate Encore™ 26 Advantage Kit (K123214).

The proposed Encore™ 26 Advantage Kit Insertion Tool device component incorporates substantially equivalent design, fundamental technology, manufacturing processes, packaging, sterilization and intended use as the SCIMED AVENUE Coronary Guidewire Insertion Tool device cleared for marketing under K922410.

Comparison to Predicates:

Characteristic	**Proposed compared to Predicates**
Mechanism of Action	Same mechanism of action.
Components	Same components, configuration, design and function.
Materials	Modified Insertion Tool has equivalent materials (sheath and hub colorant).
Packaging	Same packaging materials and packaging configuration.
Sterilization Method/SAL	Same method and level of sterility assurance.
Device Compatibility	Same compatibility.
Device Dimensions	Modified Insertion Tool has equivalent dimensions.
Biocompatibility	Same biocompatibility.

Performance Data	Design Verification and Design Validation Testing was performed to verify that the performance and usability of the modified Insertion Tool remains substantially equivalent to the predicate device via K140673. In addition Sterilization, Packaging and Biocompatibility testing verifies the overall substantial equivalence to the kit predicate. No additional testing was required for kit inclusion. No new safety or performance issues were raised during the device testing. Therefore, these devices may be considered substantially equivalent to the predicate device.
Conclusion	Based on the indications for use, technological characteristics, safety and performance testing, the proposed Encore™ 26 Advantage Kit has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the Encore™ 26 Advantage Kit as submitted in K123214 and the SCIMED AVENUE Coronary Guidewire Insertion Tool as submitted in K922410.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 17, 2014

Boston Scientific Corporation
c/o Lisa Mee
Senior Regulatory Affairs Specialist
One Scimed Place
Maple Grove, MN 55311

Re: K140745
Trade/Device Name: Encore™ 26 Advantage Kit
Regulation Number: 21 CFR 870.1650
Regulation Name: Balloon Inflation Kit
Regulatory Class: II
Product Code: MAV
Dated: March 24, 2014
Received: March 25, 2014

Dear Ms. Mee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K140745

Device Name: Encore™ 26 Advantage Kit

Indications for Use:

The Encore 26 Advantage Kit is a kit of sterile disposable devices intended of ruse as accessories for percutaneous coronary angiography (PTCA) procedures. They allow for balloon inflation and wire control.

- Encore™ 26 Inflation Device: indicated for use with balloon dilatation catheters to create and monitor pressure in the balloon, and to deflate the balloon.
- Gateway™ Plus Y-Adaptor: used for providing hemostasis around balloon dilatation catheters, guidewires and other therapeutic devices during general intravascular procedures.
- Torque Device: used for guidewire manipulation during general intravascular procedures.
- Insertion Tool: used to facilitate the introduction of a guidewire during general intravascular procedures.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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